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Achim Quaiser

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PILLSBURY WINTHROP SHAW PITTMAN LLP

ATTENTION: DOCKETING DEPARTMENT

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EXAMINER

STEELE, AMBER D

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1639

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,708	Applicant(s) QUAISER ET AL.	
	Examiner Amber D. Steele	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40,42-47 and 53-76 is/are pending in the application.
- 4a) Of the above claim(s) 60-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,7,40,42 and 53-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. The preliminary amendment received on February 18, 2005 canceled claims 1-39 and added new claims 40-76.

The amendment to the claims received on August 6, 2008 amended claims 40, 43, 46, and 53 and canceled claims 41 and 48-52.

Claims 40, 42-47, and 53-76 are currently pending.

Claims 40, 42-47, and 53-59 are currently under consideration.

Election/Restrictions

2. Applicants elected, with traverse, Group I (previous claims 40-59) in the reply filed on March 12, 2008. Claims 60-76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

3. Applicants elected, without traverse, the first layer arranged above the second layer as the species of arrangement in the reply filed on March 12, 2008. Claims 48-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

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4. Please note: the change in dependency of present claim 53 from claim 51 (withdrawn from consideration due to species election) to present claim 40 requires present claim 53 to be examined on the merits in the present Office action.

Priority

5. The present application claims status as a 371 (national stage) of PCT/EP03/09223 filed August 20, 2003. In addition, the present application claims foreign priority to EP 02018210.1 filed August 20, 2002.

Specification

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

7. The use of the trademarks Sepharose™, Sephadex™, Sephacryl™, BioGel™, and Superose™ have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Invention as Claimed

8. A device for the isolation and/or purification of nucleic acid molecules comprising at least two layers: a first layer being adapted to bind or inactivate inhibitors of the activity of reagents or enzymes used in nucleic acid manipulation wherein said first layer comprises

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polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP) and a second layer being adapted to separate a plurality of nucleic acid molecules with respect to their size and wherein said first layer is a first phase of a gel and said second layer is a second phase of said gel and wherein said first layer is arranged above the second layer and variations thereof.

9. Please note: the specification, page 35, last paragraph states that approximately 1/4, 1/3, or up to 80-95% of the gel can be one layer. In addition, “above” is defined as vertical or horizontal (see page 8).

Please refer to MPEP § 2114 regarding apparatus claims, MPEP § 2115 regarding materials worked upon by the apparatus, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function (*In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997)), recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus, expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim (*Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969)), and inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims (*In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) and as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Withdrawn Objection

10. The objection to the specification is withdrawn in view of the full citations listed previously.

Withdrawn Rejection

11. The rejection of claims 40-46 and 54-59 under 35 U.S.C. 102(b) as being anticipated by Coffman WO 99/00168 published January 7, 1999 (provided by applicants in the IDS) is withdrawn in view of the claim amendments received on August 6, 2008 (i.e. PVP or PVPP first layer).

Maintained Rejection

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The rejection may have been altered to reflect the claim amendments received on August 6, 2008.

Claim Rejections - 35 USC § 102

13. Claims 40, 42-47, and 53-59 are rejected under 35 U.S.C. 102(b) as anticipated by Young et al. Applied and Environmental Microbiology 59(6): 1972-1974, 1993 (provided by applicants in the IDS).

For present claims 40, 42-47, and 54-59, Young et al. teach agarose gel electrophoresis to provide rapid and simple purification of DNA from soil comprising a PVP-LMP agarose gel (i.e. further comprising nucleic acids) wherein the second phase of the gel is substantially free of PVPP, CTAB, EDTA, EGTA, cyclodextrins, proteins, polypeptides, antibodies, aptamers,

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lectins, or ion-exchangers; electricity is utilized to flow a sample through the gel; the gel has a sample loading means provided in a defined array of columns (i.e. where comb has been removed forming wells in gel which form columns after the sample has been run through the gel); DNA; and soil (please refer to the entire reference particularly the abstract; Figure 1; page 1972). Please refer to MPEP § 2114 and § 2115.

Therefore, the presently claimed invention is anticipated by the teachings of Young et al.

Arguments and Response

14. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Young et al. for claims 40, 42-47, and 54-59 were considered but are not persuasive for the following reasons.

Applicants contend that Young et al. teach addition of PVP to a standard agarose gel which is a single layer and does not teach a device with two layers.

Applicants' arguments are not convincing since the teachings of Young et al. anticipate the device of the instant claims. Young et al. teach a PVP-agarose gel (please refer to the entire specification particularly page 1972). Regarding applicants' contention that Young et al. do not teach a two layer device, it is noted that the two layers as presently claimed are not necessarily structurally different. The "first layer" comprises PVP or PVPP (see present claim 1) and further comprises (a) CTAB, EDTA, EGTA, cyclodextrins, proteins, polypeptides, antibodies, aptamers, lectins, nucleic acids, or ion-exchangers (see present claim 43) and/or (b) a sample loading means (see present claim 46). While the "second layer" must be substantially free of PVP, PVPP, CTAB, EDTA, EGTA, cyclodextrins, proteins, polypeptides, antibodies, aptamers, lectins, nucleic acids, or ion-exchangers (see present claim 44) and may consist of "agarose,

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Sepharose™, Sephadex™, Sephacryl™, BioGel™, Superose™, or acrylamide” (see present claim 53). In addition, the first or second layer must be arranged such that the first layer is above the second layer, the first layer is a “first phase of a gel”, and the second layer is a “second phase of a gel” (see present claim 40). Therefore, the presently claimed invention reads on various species of device including a PVP-agarose gel wherein the first phase (i.e. first layer) is above a second phase (i.e. second layer). For example, the first phase could be designated as the section of the gel separating nucleic acids larger than 600 kbp and the second phase could be designated as the section of the gel separating nucleic acids smaller than 600 kbp (see present Figure 5B). Alternatively, the first phase of the gel could be the sample loading area and the second phase of the gel could be the area wherein the samples run.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a **new matter** rejection.

Claim 43 recites “said first layer further comprises CTAB, EDTA, EGTA, cyclodextrins, proteins, (poly)peptides, antibodies, aptamers, lectins, nucleic acids or an ion-exchanger”.

Applicants state that the amendment to claim 43 was “made in view of the foregoing amendment to claim 40” (see page 7, second paragraph of the response received on August 6, 2008).

However, claim 43 originally claimed PVP, PVPP, CTAB, EDTA, EGTA, cyclodextrins, proteins, (poly)peptides, antibodies, aptamers, lectins, nucleic acids, and an ion-exchanger in the alternative only, therefore, a combination of (a) PVP or PVPP and (b) CTAB, EDTA, EGTA, cyclodextrins, proteins, (poly)peptides, antibodies, aptamers, lectins, nucleic acids or an ion-exchanger in the first layer was not disclosed in the claims. Thus, applicants have not specifically pointed out support for the claim amendment in the specification as originally filed (see MPEP § 2163.06).

If applicants disagree, applicants should present a detailed analysis as to why the claimed subject matter has clear support in the specification.

17. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claim 53 contains the trademarks/trade names Sepharose™, Sephadex™, Sephacryl™, BioGel™, and Superose™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does

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not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe components of the first or second layer and, accordingly, the identification/description is indefinite.

19. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, independent claim 40 requires that the “first layer comprises polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP)” (i.e. open claim language regarding the composition of the first layer) while dependent claim 53 requires the first layer (or second layer) to be “selected from the group consisting of agarose, Sepharose™, Sephadex™, Sephacryl™, BioGel™, Superose™, and acrylamide” (i.e. closed claim language). Therefore, it is not clear to one of skill in the art what the composition of the first layer must be (e.g. PVP, agarose, PVP and agarose, etc.).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 40, 42-46, and 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffman WO 99/00168 published January 7, 1999 (provided by applicants in the IDS) and Berthelet et al., 1996, Rapid, direct extraction of DNA from soils for PCR analysis using

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polyvinylpolypyrrolidone spin columns, FEMS Microbiology Letters, 138: 17-22 (provided by applicants in the IDS).

For present claims 40, 42-46, and 53-59, Coffman teach a two phase column comprising a top layer of adsorptive media and a second layer of size exclusion media wherein various adsorptive media can be utilized including commercially available reagents comprising agarose and the first adsorptive layer is utilized to extract various components of the sample including proteins (i.e. second layer substantially free of proteins, etc.) wherein proteins can be separated from DNA and/or RNA (please refer to the entire specification particularly the abstract; pages 2-10; Figures 1-2). Please refer to MPEP § 2114 and 2115.

However, Coffman does not teach a first layer comprising PVP or PVPP.

For present claims 40, 42-46, and 53-59, Berthelet et al. teach utilizing PVPP columns to extract DNA from soil samples (please refer to the entire reference particularly the abstract; Materials and Methods section).

The claims would have been obvious because the substitution of one known element (i.e. various column material taught by Coffman) for another (i.e. PVPP column material taught by Berthelet) would have yielded predictable results (i.e. extraction of DNA) to one of ordinary skill in the art at the time of the invention. In addition, the claims would have been obvious because a particular known technique (i.e. two phase chromatography taught by Coffman and PVPP column extraction of DNA taught by Berthelet) was recognized as part of the ordinary capabilities of one skilled in the art. Furthermore, Berthelet et al. teach that the PVPP columns provided rapid separation and enhanced the removal of inhibitory humic acid contaminants from

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soil extracts resulting in purer preparations of DNA more suitable for PCR (see page 20, section 3). See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Patent Examiner, Art Unit 1639

November 4, 2008